

### **REMARKS/ARGUMENTS**

The foregoing amendments in the claims are of formal nature, and do not add new matter. Claims 28-35, 38-40 and 44-54 are pending in this application and were rejected on various grounds. The rejection of the remaining claims is respectfully traversed.

#### **Priority**

Applicants note the effective filing date of November 30, 1999 for the subject matter defined in Claims 28-35, 38-40 and 44-54.

#### **The Office Action**

Applicants appreciate the withdrawal of the earlier objection regarding the use of trademarks, the rejection of Claim 46 under 35 U.S.C. §101, the rejection of Claims 28-33, 37 and 41 under 35 U.S.C. §112, second paragraph, the rejection of Claim 42 under 35 U.S.C. §112, second paragraph, the rejection of Claims 28-32 and 41-47 under 35 U.S.C. §112, first paragraph, for lack of enablement and the rejection of Claims 28-32 and 41-47 under 35 U.S.C. §112 for lack of written description.

#### **Claim Rejections – 35 U.S.C. §112, Second Paragraph**

Claims 28-36, 38-41 and 43-47 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner noted that the rejection could be obviated by amending the claims so that they are drawn to nucleic acid molecules wherein the "encoded polypeptide stimulates endothelial cell growth or the polypeptide induces proliferation of kidney mesangial cells." (See page 4 of instant Office Action).

Without acquiescing to the Examiner's position in the current rejection and solely in the interest of expediting prosecution in this case, Applicants have amended Claims 28-32 (and, as a consequence, those claims dependent from the same) to recite "encoded polypeptide stimulates endothelial cell growth or the polypeptide induces proliferation of kidney mesangial cells." Hence, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

### **Claim Rejections – 35 U.S.C. §102**

Claims 28-32, 38-40 and 44-47 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0096951 (Jacobs *et al.*, effective filing date August 13, 1999, publication date May 22, 2003). Examiner alleges that SEQ ID NO: 3 encoding the polypeptide of SEQ ID NO: 4 disclosed in Jacobs *et al.* is 92.8% identical to SEQ ID NO: 129 of the present application.

Applicants respectfully submit the attached Declaration signed by all of the inventors, Dr. Ferrara, Dr. Goddard, Dr. Godowski, Dr. Gurney, Dr. Pan, Mr. Watanabe and Dr. Wood, the consideration of which is respectfully requested.

### **Applicants simply need to disclose what is disclosed in the cited reference to support the priority claim**

Applicants respectfully submit that the Declaration by Dr. Ferrara, Dr. Goddard, Dr. Godowski, Dr. Gurney, Dr. Pan, Mr. Watanabe and Dr. Wood ("Declaration") simply needs to provide a disclosure commensurate in scope with the disclosure in the priority document by Jacobs *et al.* to support the priority claim.

In order to remove a reference as a prior art, "[i]t is sufficient if [the affidavit under Patent Office Rule 131] shows that as much of the claimed invention as is taught in the reference has been reduced to practice by the [patentee] prior to the date of the reference." *In re Stempel*, 241 F.2d 755, 757 (1957). In *In re Stempel*, the patent applicant (Stempel) had claims directed to both (i) a particular genus of chemical compounds (the "generic" claim) and (ii) a single species of chemical compound that was encompassed within that genus (the "species" claim). In support of a rejection under 35 U.S.C. §102, the examiner cited against the application a prior art reference that disclosed the exact chemical compound recited in the "species" claim. In response to the rejection, the patent applicant filed a declaration under 37 C.F.R. §1.131 demonstrating that he had made that specific chemical compound prior to the effective date of the cited prior art reference. The Court found the applicant's 131 declaration effective for swearing behind the cited reference for purposes of both the "species" claim and the "genus" claim. Specifically, the Court stated in support of its decision that "all the applicant can be required to show is priority

with respect to so much of the claimed invention as the reference happens to show. When he has done that he has disposed of the reference." *Id.* at 759.

Furthermore, the Examiner is respectfully directed to *In re Moore*, 170 USPQ 260 (CCPA 1971), where the holding in *In re Stempel* was affirmed. In *In re Moore*, the patent applicant claimed a particular chemical compound in his patent application and the examiner cited against the applicant a prior art reference under 35 U.S.C. §102 rejection which disclosed the compound but did not disclose any specific utility for the compound. The patent applicant filed a declaration under 37 C.F.R. §1.131 demonstrating that he had made the claimed compound before the effective date of the cited prior art reference, even though he had not yet established a utility for that compound. On appeal, the Court indicated that the 131 declaration filed by the patent applicant was sufficient to remove the cited reference. The Court relied on the established "Stempel Doctrine" to support its decision, stating:

An applicant need **not** be required to show [in a declaration under 37 C.F.R. §1.131] any more acts with regard to the subject matter claimed that can be carried out by one of ordinary skill in the pertinent art following the description contained in the reference ... the determination of a practical utility when one is not obvious need **not** have been accomplished prior to the date of a reference unless the reference also teaches how to use the compound it describes.

*In re Moore*, 170 USPQ at 267 (emphasis added).

Thus, *In re Moore* confirmed the holding in *In re Stempel* which states that in order to effectively remove a cited reference with a declaration under 37 C.F.R. §1.131, an applicant need only show that portion of his or her claimed invention that appears in the cited reference.

Accordingly, Applicants respectfully submit that the Declaration simply need to show possession of the polypeptide sequence and its encoding polynucleotide sequence disclosed in Jacobs *et al.* in order to remove Jacobs *et al.* as a prior art reference.

The cited Publication No. 2003/0096951 and the priority document 60/096,622 by Jacobs *et al.* disclose a polypeptide (SEQ ID NO: 4), which is identical to the PRO1244 polypeptide sequence (SEQ ID NO: 130) of the present application. However, the cited Publication No. 2003/0096951 does not teach that the polypeptide of SEQ ID NO: 4 is capable of stimulating adrenal cortical capillary endothelial cell (ACE) growth or inducing proliferation of mammalian

kidney mesangial cells. Accordingly, Publication No. 2003/0096951 and the priority document merely disclose the amino acid sequence identical to the PRO1244 polypeptide and its encoding nucleic acid sequence that is 92.8% identical to SEQ ID NO: 129, but are devoid of any experimental data demonstrating the ACE growth stimulation activity or the mesangial cell proliferation induction activity as disclosed in the present application.

As shown in the Declaration, Applicants respectfully submit that Dr. Ferrara, Dr. Goddard, Dr. Godowski, Dr. Gurney, Dr. Pan, Mr. Watanabe and Dr. Wood cloned and sequenced PRO1244 polypeptide (SEQ ID NO: 130) and its encoding nucleic acid sequence (SEQ ID NO: 129), in the United States prior to August 14, 1998.

As indicated in the Declaration and the brief description of Figure 73 of the present specification, the PRO1244 polypeptide is encoded by DNA 64883-1526.

Furthermore, as stated in the Declaration, the GSeqEdit database stores cloning and sequencing information for each PRO polypeptide and its encoding nucleic acid sequences according to its DNA number. Copies of the pages from the GSeqEdit database report (with the dates redacted) showing the cloning and sequencing information for the PRO1244 polypeptide sequences and its encoding nucleic acid sequence are attached to the Declaration as Exhibit A.

The GSeqEdit report shows the full length nucleic acid sequence for DNA-64883-1526 (identified as "DNA-64883") and the full length polypeptide sequence encoded by DNA 64883. As evidenced from the report and stated in the Declaration, both the nucleic acid and amino acid sequences shown in Exhibit A were obtained prior to August 14, 1998.

In addition, as stated in the Declaration, the DNA-64883 sequence shown in the GSeqEdit report is identical to the SEQ ID NO: 129 disclosed in the present application. The amino acid sequence shown in the GSeqEdit report is also identical to SEQ ID NO: 130 disclosed in the present application and to SEQ ID NO: 4 in Jacobs *et al.*

Accordingly, the attached Exhibit A clearly shows that Applicants were in possession of DNA-64883-1526 and the PRO1244 polypeptide encoded by DNA 64883-1526, as claimed in the present application, prior to August 14, 1998. Consequently, based on the teachings of *In re Stempel* and *In re Moore*, Applicants respectfully submit that Jacobs *et al.* is not prior art under 102(e) since its publication date and its effective filing date are after the effective priority date of


the present application. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

All claims pending in the present application are believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641, referencing Attorney's Docket No. 39780-2830 P1C47). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: October 25, 2004

By:   
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